CLAIMS

We claim:

1. A method of using tizanidine in the treatment of spasticity comprising:

informing a patient in need of treatment that administration of a therapeutically effective amount of tizanidine in an immediate release pharmaceutical tablet formulation, with food, results in an increased extent of tizanidine absorption as compared to administration of an immediate release pharmaceutical tablet formulation without food;

wherein the patient administers the pharmaceutical tablet formulation with food.

2. The method of claim 1, wherein the therapeutically effective amount is 0.5 mg to 12 mg.

3. The method of claim 2, wherein the therapeutically effective amount is 2 mg to 8 mg.

4. The method of claim 1, wherein the administration to the patient occurs from about 30 minutes prior to about 2 hours after consuming food.

5. The method of claim 4, wherein the administration to the patient is substantially at the same time as the consumption of the food.

6. The method of claim 1, wherein the administration to the patient is immediately after the consumption of food up to 1 hour after said consumption.

7. A method of using tizanidine in the treatment of spasticity comprising:

informing a patient that an increase in bioavailability is achieved when a therapeutically effective amount of tizanidine is administered with food; and

administering to the patient a therapeutically effective amount of tizanidine in an immediate release tablet, with food.

8. The method according to claim 7, wherein administering to the patient a therapeutically effective amount of tizanidine in an immediate release tablet, with food, results in an increase in AUC(last) of about 28 percent.

9. The method according to claim 8, wherein the therapeutically effective amount is 0.5 mg to 12 mg.

10. The method according to claim 9, wherein the therapeutically effective amount is 2 mg to 8 mg.

11. The method according to claim 7, wherein the immediate release tizanidine tablet is from a container with printed labeling advising that administration with food results in an increase in the extent of absorption (AUC(last)) of tizanidine compared to administration without food.

12. A method of increasing the extent of absorption of tizanidine from a tablet, in a patient in need of a therapeutic effect thereof, comprising:

administering to the patient a therapeutically effective amount of tizanidine in a pharmaceutical composition with food, wherein the tizanidine tablet is from a container with printed labeling advising that administration with food results in an increase in the extent of absorption (AUC(last)) of tizanidine compared to administration without food.

13. The method according to claim 12, wherein administering to the patient a therapeutically effective amount of tizanidine in a pharmaceutical composition in tablet form with food results in an increase in AUC(last) of at least about 25 percent.

14. The method according to claim 13, wherein administering to the patient a therapeutically effective amount of tizanidine in a pharmaceutical composition with food results in an increase in AUC(last) of 28 percent.

15. The method according to claim 12, wherein the therapeutically effective amount is about 0.5 mg to about 12 mg.

16. The method according to claim 15, wherein the therapeutically effective amount is from about 2 mg to about 8 mg.

17. A method of increasing the oral bioavailability of tizanidine to a patient receiving tizanidine therapy comprising:

informing a patient in need of treatment that administration of a therapeutically effective amount of tizanidine in an immediate release pharmaceutical tablet formulation, with food, results in an increased extent of tizanidine absorption as compared to administration of an immediate release pharmaceutical tablet formulation without food; and

administering to the patient one or more pharmaceutical tablet(s) comprising 2 mg to 8 mg of tizanidine, with food, wherein the administration results in an increase in the extent of absorption (AUC(last)) of tizanidine compared to administration without food.

18. The method of claim 17, wherein the therapeutically effective amount of tizanidine is 8 mg, and wherein administration without food results in an AUC(last) of tizanidine of from about 6.93 to about 24.63 ng*hr/mL.

19. The method of claim 18, wherein the therapeutically effective amount of tizanidine is 8 mg, and wherein administration without food results in an AUC(last) of tizanidine of from about 12.62 to about 19.73 ng*hr/mL.

20. The method of claim 19, wherein the therapeutically effective amount of tizanidine is 8 mg, and wherein administration without food results in an AUC(last) of tizanidine of from about 14.79 to about 16.80 ng*hr/mL.

21. The method of claim 17, wherein the therapeutically effective amount of tizanidine is 8 mg, and wherein administration with food results in an AUC(last) of tizanidine of from about 11.46 to about 29.61 ng*hr/mL.

22. The method of claim 21, wherein the therapeutically effective amount of tizanidine is 8 mg, and wherein administration with food results in an AUC(last) of tizanidine of from about 16.24 to about 25.39 ng*hr/mL.

23. The method of claim 22, wherein the therapeutically effective amount of tizanidine is 8 mg, and wherein administration with food results in an AUC(last) of tizanidine of from about 19.32 to about 21.30 ng*hr/mL.

24. The method of claim 17, wherein the therapeutically effective amount of tizanidine is 8 mg, and wherein administration without food results in a Cmax of tizanidine of from about 3.19 to about 7.67 ng/mL.

25. The method of claim 24, wherein the therapeutically effective amount of tizanidine is 8 mg, and wherein administration without food results in a Cmax of tizanidine of from about 4.34 to about 6.79 ng/mL.

26. The method of claim 25, wherein the therapeutically effective amount of tizanidine is 8 mg, and wherein administration without food results in a Cmax of tizanidine of from about 5.18 to about 5.68 ng/mL.

27. The method of claim 17, wherein the therapeutically effective amount of tizanidine is 8 mg, and wherein administration with food results in a Cmax of tizanidine of from about 4.57 to about 9.03 ng/mL.

28. The method of claim 27, wherein the therapeutically effective amount of tizanidine is 8 mg, and wherein administration with food results in a Cmax of tizanidine of from about 5.44 to about 8.5 ng/mL.

29. The method of claim 28, wherein the therapeutically effective amount of tizanidine is 8 mg, and wherein administration with food results in a Cmax of tizanidine of from about 6.55 to about 7.05 ng/mL.

30. A method of tizanidine therapy comprising:

informing a patient that administration of a therapeutically effective amount of tizanidine in tablet form, with food, results in an increase in the extent of absorption AUC(last) of tizanidine, compared to administration without food.

31. A method of tizanidine therapy comprising:

informing a patient to administer a therapeutically effective amount of tizanidine, as a tablet, with food.

32. A method for improving tizanidine therapy comprising:

packaging a pharmaceutical tablet formulation of tizanidine with information that administration of the tizanidine with food increases the extent of absorption (AUC(last)) of tizanidine compared to administration without food; and

supplying the pharmaceutical tablet formulation to patients in need of tizanidine therapy.

33. A method for increasing the oral bioavailability of tizanidine comprising:

administering a tizanidine tablet from a container providing information that administration of the tizanidine tablet with food results in an increase in the extent of absorption (AUC(last)) of tizanidine compared to administration without food, wherein the tablet is administered with food.

34. A method of providing tizanidine tablets to patients comprising:

preparing a pharmaceutical tablet formulation of tizanidine;

packaging the formulation with information advising that administration of the tablet formulation with food results in an increase in extent of tizanidine absorption, to produce a packaged tablet formulation; and

supplying the packaged tablet formulation to patients in need of tizanidine therapy.

35. A method of improving tizanidine therapy, the improvement comprising taking a tizanidine tablet with food, with the purpose of enhancing tizanidine bioavailability.

36. A method of improving tizanidine therapy, the improvement comprising providing a tizanidine tablet formulation with information that advises a patient to take the tizanidine tablet with food.

37. A manufacture comprising:

a container containing a pharmaceutical tablet composition of tizanidine, wherein the container is associated with printed labeling advising that

taking the composition with food increases the extent of absorption of tizanidine to a patient receiving the composition by oral administration.

38. A manufacture comprising:

a pharmaceutical tablet composition of tizanidine in a container, wherein the container is associated with information that administration of the tizanidine with food results in an increase in the extent of absorption (AUC(last)) of tizanidine compared to administration without food.

39. An item of manufacture comprising a container containing an immediate release pharmaceutical composition of tizanidine or a pharmaceutically acceptable salt thereof, wherein the container is associated with printed labeling advising that an immediate release tablet composition has an increased extent of absorption associated with its use if taken with food.